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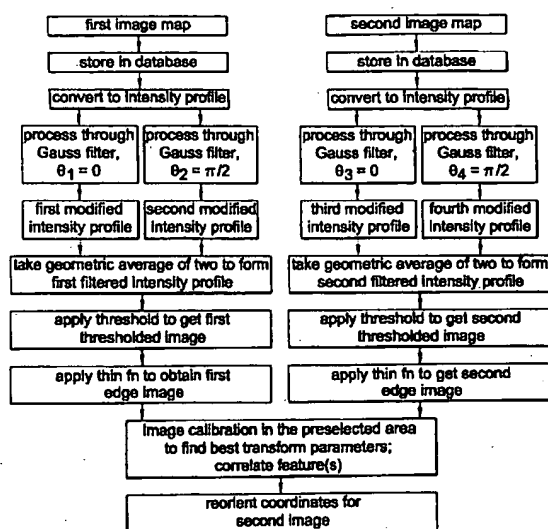
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(54) Title: EYE REGISTRATION AND ASTIGMATISM ALIGNMENT CONTROL SYSTEMS AND METHOD



(57) Abstract: An orientation system for corrective eye surgery includes a camera for performing a first image mapping a patient's eye using a predetermined eye feature and software for processing the first image map to determine an edge location of the feature. A second image mapping is performed with the patient in a different position. The second image map is processed to locate the feature. In a second embodiment a pen is used to make two alignment marks on the eye. The eye is imaged with the patient in another position, and the image displayed. Software superimposes a graphical reticle onto the eye image, which is movable to align with the two alignment marks. In both cases software also calculates an orientational change to be applied to a corrective prescription for a surgical procedure to be performed on the eye with the patient in the second position.

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## **EYE REGISTRATION AND ASTIGMATISM ALIGNMENT CONTROL SYSTEMS AND METHOD**

### **BACKGROUND OF THE INVENTION**

#### **Cross-Reference to Related Application**

This application claims priority from and incorporates by reference commonly owned provisional applications Serial No. 60/198,393, filed April 19, 2000, "Astigmatism Alignment Control Device and Method," and Serial No. 60/270,071, filed February 20, 2001, "Eye Registration Apparatus and Method."

#### **Field of the Invention**

The present invention relates to systems and methods for improving objective measurements preceding corrective eye surgery, and, more particularly, to such systems and methods for improving results of corrective laser surgery on the eye.

#### **Description of Related Art**

Laser-in-situ-keratomileusis (LASIK) is a common type of laser vision correction method. It has proven to be an extremely effective outpatient procedure for a wide range of vision correction prescriptions. The use of an excimer laser allows for a high degree of precision and predictability in shaping the cornea of the eye. Prior to the LASIK procedure, measurements of the eye are made to determine the amount of corneal material to be removed from various locations on the corneal surface so that the excimer laser can be calibrated and guided for providing the corrective prescription previously determined by the measurements. Refractive laser surgery for the correction of astigmatism typically requires that a cylindrical or quasicylindrical ablation profile be applied to the eye. The long axis of this profile must be properly oriented on the eye in order to accurately correct the visual aberration.

An objective measurement of a patient's eye is typically made with the patient typically sitting in an upright position while focusing on a target image. A wavefront analyzer then objectively determines an appropriate wavefront correction for reshaping the cornea for the orientation of the eye being examined. The LASIK or PRK procedure is then typically performed with the patient in a prone position with the eye looking upward.

It is well known that the eye undergoes movement within the socket comprising translation and rotation ("cyclotortion") as the patient is moved from the upright measuring position to the prone surgery position. Techniques known in the art for accommodating this movement have included marking the eye by cauterizing reference points on the eye using a cautery instrument (U.S. Pat. No. 4,476,862) or caustic substance, a very uncomfortable procedure for the patient. It is also known to mark a cornea using a plurality of blades (U.S. Pat. No. 4,739,761). The injection of a dye or ink is also used to mark the reference locations to identify the orientation of the eye during measurement, permitting a positioning of the corrective profile to the same orientation prior to surgery. However, the time delay from measurement to surgery often causes the ink to run, affecting the accuracy of an alignment. Making an impression on the eye (U.S. Pat. No. 4,705,035) avoids the caustic effects of cauterizing and the running effect of the ink. However, the impression loses its definition quickly relative to the time period between the measurement and surgery.

For correction of astigmatism, it is known to mark the cornea preparatory to making the surgical incisions (U.S. Pat. No. 5,531,753).

Tracker systems used during the surgical procedure or simply for following eye movement, while the patient is in a defined position, are known to receive eye movement data from a mark on a cornea made using a laser beam prior to surgery (U.S. Pat. No. 4,848,340) or from illuminating and capturing data on a feature in or on the eye, such as a retina or limbus, for example (U.S. Pat. Nos. 5,029,220; 5,098,426; 5,196,873; 5,345,281; 5,485,404; 5,568,208; 5,620,436; 5,638,176; 5,645,550; 5,865,832; 5,892,569; 5,923,399; 5,943,117; 5,966,197; 6,000,799; 6,027,216).

### **SUMMARY OF THE INVENTION**

It is therefore an object of the present invention to provide a system and method for accurately orienting the eye for surgery.

It is a further object to provide such a system and method that orients the eye to the same orientation it had during an objective measurement.

It is another object to provide such a system and method that avoids placing the patient in an uncomfortable or harmful situation.

It is an additional object to provide such a system and method that provides an orientation correction algorithm to the software driving the corrective surgical device.

5 It is yet a further object to provide such a system and method that can align (register) pairs of eye images taken at different times.

These and other objects are achieved by the present invention, an orientation system for corrective eye surgery. A first embodiment of the system comprises means for performing a first image mapping an eye of a patient situated in a first position using a predetermined eye feature and means for processing the first image map to determine an edge location of the feature in two dimensions. Means are further provided for performing a second image mapping of the eye of the patient in a second position different from the first position using the predetermined eye feature. Means are also provided for processing the second image map to locate the predetermined eye feature. Finally, software means are included for calculating an orientational change to be applied to a corrective prescription for a surgical procedure to be performed on the eye with the patient in the second position. The procedure may comprise, for example, a correction profile that had been determined with the patient in the first position with, for example, a wavefront analysis and conversion system for calculating an ablation profile for a cornea, such as described in copending and co-owned application Serial No. 09/566,668, the disclosure of which is hereby incorporated by reference.

The method of this first embodiment of the present invention is for orienting a corrective program for eye surgery and comprises the steps of performing a first image mapping of an eye of a patient in a first position using a predetermined eye feature and processing the first image map to determine an edge location of the feature in two dimensions. The method also comprises the steps of performing a second image mapping of the eye of the patient in a second position different from the first position using the feature and processing the second image map to locate the feature. Next an orientational change to be applied to a corrective prescription for a surgical procedure to be performed on the eye with the patient in the second

position is calculated. The procedure comprises a correction profile determined with the patient in the first position.

Thus this aspect of the present invention provides a system and method for achieving a precise registration of the eye with a measurement of the movement of an eye feature. As a result, the prescription measurement for reshaping the cornea will account for the rotation and translation of the eye occurring between measurements made with the patient in a sitting position and laser surgery with the patient in a prone position.

A second orientation system for eye surgery for correcting astigmatism comprises means for making two alignment marks on an eye of a patient with the patient in a first position. Means are also provided for imaging the eye with the patient in a second position that is different from the first position. The system also comprises a computer that has input and output means. The input means are in electronic connection with the imaging means, and an operator input device is in electronic communication with the computer input means. Means are also in communication with the computer input and output means for displaying the eye image to an operator.

First software means are resident in the computer for superimposing a graphical reticle means onto the eye image on the displaying means and for permitting the graphical reticle means to be moved by the operator under control of the operator input means. The reticle means comprise a line for aligning with the two alignment marks. Second software means also resident in the computer are for calculating an orientational change to be applied to a corrective surgical procedure to be performed on the eye with the patient in the second position. As above, the procedure comprises a correction profile determined with the patient in the first position.

The features that characterize the invention, both as to organization and method of operation, together with further objects and advantages thereof, will be better understood from the following description used in conjunction with the accompanying drawing. It is to be expressly understood that the drawing is for the purpose of illustration and description and is not intended as a definition of the limits

of the invention. These and other objects attained, and advantages offered, by the present invention will become more fully apparent as the description that now follows is read in conjunction with the accompanying drawing.

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### **BRIEF DESCRIPTION OF THE DRAWINGS**

FIG. 1 is a schematic diagram of the system of the first embodiment of the present invention.

FIG. 2 is a block diagram of the data flow.

FIG. 3 is a view of the original image, before image processing, with feature  
10 boxes around the features to be used as registration regions.

FIG. 4 is a view of a Gauss-filtered intensity profile with  $\theta_1 = 0$ , showing the edge in an x direction.

FIG. 5 is a view of a Gauss-filtered intensity profile with  $\theta_2 = \pi/2$ , showing the edge in a y direction.

15 FIG. 6 is a view of a geometric average of FIGS. 4 and 5.

FIG. 7 is a view with threshold application.

FIG. 8 is a view of the image following application of the thin function.

FIG. 9 is a schematic diagram of the system of the second embodiment of the present invention.

20 FIG. 10 is a representation of an image of an eye as viewed on a graphical user interface in the second embodiment of the invention.

### **DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS**

25 A description of the preferred embodiments of the present invention will now be presented with reference to FIGS. 1–10.

#### **The System and Method of the First Embodiment**

A schematic diagram of the system 10 of the first embodiment of the invention is shown in FIG. 1, data flow in FIG. 2, and original and processed images in FIGS.  
30 3–8. A section on the image processing algorithms embodied herein follows the description of the system and method. In an exemplary embodiment of the system

10, a patient's eye 11 is image mapped in a substantially upright position by capturing a first video image 12 using a camera such as a charge-coupled-device (CCD) camera 13. Such an image 12 is illustrated in FIG. 3. The first image 12 is stored in a database 14 in electronic communication with a computer 15 and labeled as an original image from a first measurement.

Next an objective measurement is made on the eye 11 to determine a desired correction profile, using a measurement system 16 such as that disclosed in copending application 09/566,668, although this is not intended as a limitation.

Once the correction profile is determined, the patient is made ready for surgery, and placed in the second position, which is typically prone. Alternatively, the first scan to determine the correction profile may be made in a different location and at a time prior to the surgical procedure, the time interval being, for example, several weeks. Then a second image map 17 is collected using a second camera 18, in communication with a second system 38 for performing surgery, and these data are also stored in the database 14. In a preferred embodiment both the first 13 and the second 18 cameras are adapted to collect color images, and these images are then converted using software resident on the computer 15 to intensity profiles 19,20 as grey-scale images. Alternatively, color images may be used. It is useful to collect color images for viewing by the physician, since image mapping of the eye 11 may be made using preselected identifiable images such as blood vessels 21,22 typically seen within the sclera 23. In a color image, the red color of the vessels 21,22 is clearly identifiable. Typically the second image map 17 is collected during setup prior to surgery using a correction system 23 such as is disclosed in application Serial No. 09/566,668, although this is not intended as a limitation. As the image maps 12,17 are typically collected with different cameras 13,18, the qualities of the images 12,17 are expected to be different, making the image processing steps of great importance.

Next the intensity profile 19 of the first video image 12 is processed through weighting function such as a filter, in a preferred embodiment a Gauss filter, although this is not intended as a limitation. This filter is for eliminating noise within the intensity profiles for defining image edge locations in both an x and a y orientation

to provide two-dimensional information. The Gauss filter establishes a first modified intensity profile 24 with  $\theta_1 = 0$ , as an example, as shown in FIG. 4, an edge view in the x direction. The Gauss filter is again applied to the intensity profiles to establish a second modified intensity profile 25, with  $\theta_2 = \pi/2$ , as shown in FIG. 5, an edge view in a y direction.

A geometric average of the filtered x and y orientations is performed and processed to eliminate unwanted noise levels to form a first filtered intensity profile 26 for the first image 12, yielding a view as shown in FIG. 6, which has been calculated by taking the square root of the sum of the squares of the first 24 and the second 25 modified intensity profiles.

The above process is then repeated for the second image 17, to produce, from the second intensity profile 20, a third modified intensity profile 27 from application of a Gauss filter with  $\theta_3 = 0$  and a fourth modified intensity profile 28, with  $\theta_4 = \pi/2$ , and geometric averaging to produce a second filtered intensity profile 29.

Next an adaptive signal threshold is selected to reduce background noise for the first 26 and the second 29 filtered intensity profiles, resulting in first 30 and second 31 thresholded images, as shown in FIG. 7. The  $\lambda$  may be different for the two profiles 26,29; here  $\lambda = 0.03$ .

The profiles 26,29 are then processed through a "thin function" to produce a first 32 and a second 33 edge image (FIG. 8). This step completes the image processing. Next the surgeon selects one or more features in the eye 11, shown as a first 21 and a second 22 feature (here, blood vessels) in FIG. 3, and these are then used for correlating between filtered images for the second (surgical) position of the eye 11 with that of the first (measurement) position. Other features may also be used if sufficiently prominent blood vessels are not present. The excimer laser 36 coordinates are then reoriented to accommodate the rotation and translation that took place when moving the patient from a measurement instrument to the surgical device.

The operator proceeds to locate the limbus 34 using a graphical user interface (GUI) while viewing the still image of the eye (FIG. 3). By way of example, a fixed reticle 37 is moved in position to coincide with the limbus 34. The reticle size may



be changed, including a diameter of a circular reticle, or optionally both minor and major radius of an elliptical reticle. The operator then selects a feature or features 21,22 of the eye 11 to be used, and the above process is automatically performed by the "push of a button," which takes only seconds to complete in the exemplary embodiment.

Using the first 32 and second 33 edge images (FIG. 8), and knowing the center of the reticle 37 (circle or ellipse), the computer 15 determines coordinates 38 for the selected features 34,35.

Image mapping within each feature box 34,35 is a process of using the transformation described below. By way of example, the process fixes the first image 32 and varies the angle of orientation for second image 33.

The computer 15 overlays the first 32 and second 33 image with regard to center and compares each point within the feature box 21,22 and compares each for different value of  $\theta$ , while comparing each to determine maximum matching points. The computer 15 moves the center relation for each and seeks to improve its location (center a, b) and value for a  $\theta$  orientation. Each feature box or area (pixels within area) is processed before moving the center and is completed for every  $\theta$  (typically  $-15^\circ \leq \theta \leq +15^\circ$ , which will typically cover a patient's eye rotation when moving from an upright to a prone position. Completing the entire process takes less than 30 sec.

The treatment pattern, typically a laser shot pattern, is thus modified to account for eye rotation resulting from the patient's movement from upright to prone position. In addition, an eye tracking feature of the second system 38 can account for eye movement during surgery.

By way of further example, code for carrying out the process steps to obtain the image of FIG. 8, and code for carrying out an exemplary embodiment of the above for the steps including the feature coordinate determination through the processing of the feature boxes, were included in provisional application 60/270,071, and are incorporated herein by reference.

Another object of the present invention is to align (register) pairs of eye images taken at different times. By way of example, images may be taken at:

1. An undilated pupil at centration time on wavefront system
2. A dilated pupil at measurement time on wavefront system, using multiple measurements
3. A dilated pupil on a surgical system following formation of the flap

To align at least any two images from a mathematics point of view, it is assumed that there is enough information in each of the images to allow for the precise computation of the translational and rotational offsets between pairs of images such that any two images, by way of example, may be overlaid with acceptably small errors. This condition satisfied, an optimized linear transformation between these image pairs is determined. The transformation is described by three parameters: a translation vector  $r_0=(a,b)$  ( $a$  and  $b$  are the  $x$  and  $y$  coordinates of the translation, respectively) and a rotation angle  $\theta$ , the transformation is uniquely determined by these three parameters.

### Image Processing

The Gauss filter is used to eliminate the noise of both images and is defined as:

$$G(x, y, \sigma_1, \sigma_2) = g(u(x, y), \sigma_1) \cdot g_v(v(x, y), \sigma_2) \quad 1$$

where

$$g(u, \sigma) = \frac{1}{\sqrt{2\pi}\sigma} \exp\left(-\frac{u^2}{2\sigma^2}\right); g_v(v, \sigma) = -\frac{v}{\sigma} g(v, \sigma) \quad 2$$

and

$$u(x, y) = \cos\theta \cdot x - \sin\theta \cdot y \quad 3$$

$$v(x, y) = \sin\theta \cdot x + \cos\theta \cdot y \quad 4$$

is the rotation of the point  $(x, y)$  and  $\theta$  is the angle of rotation. Here  $\theta$  is set to be either 0 or  $\pi/2$ , which means the filter will eliminate the noise either in the  $x$  direction or the  $y$  direction. The standard deviation ( $\sigma$ ) determines the shape of the filter.

10

Let  $Im(x,y)$  represent the image data function. Applying the Gauss filter to the image function is equivalent to making the convolution of these two functions.

$$NewIm(x,y) = Im(x,y) * G(x,y,\sigma_1,\sigma_2) \quad 5$$

Next the threshold  $\xi$  is computed.

$$\xi = \lambda \cdot \max |NewIm(x,y)| + (1-\lambda) \cdot \min |NewIm(x,y)| \quad 6$$

where  $0 < \lambda < 1$ . The threshold to the new image file is applied as

$$Im N(x,y) = \begin{cases} |NewIm(x,y)| & \text{if } |NewIm(x,y)| > \xi \\ \xi & \text{otherwise} \end{cases} \quad 7$$

A bilinear interpolation method is used to determine the edge point:

$$P = (1-\alpha)[(1-\beta)P_0 + \beta P_2] + \alpha[(1-\beta)P_1 + \beta P_3] \quad 8$$

10 where gradient vector

$$\text{gradient of } Im(x,y) = (\alpha, \beta) \quad 9$$

and  $P_i$  are points in a neighborhood of  $(x,y)$ .

### Image Mapping

15 After processing both images, the best parameters in this linear transformation should be found. The "best" means that, in a given parameter space, it is desired to find a point (parameters) in that space, such that under these parameters the linear transformation minimizes the error between those pairs of images.

The linear transformation is defined as:

$$\begin{pmatrix} x' \\ y' \end{pmatrix} = \begin{pmatrix} \cos \theta & -\sin \theta \\ \sin \theta & \cos \theta \end{pmatrix} \begin{pmatrix} x - center_x \\ y - center_y \end{pmatrix} + \begin{pmatrix} a \\ b \end{pmatrix} \quad 10$$

The criterion to find the best transform parameters is to minimize the error:

$$\min_{(a,b,\theta) \in D} |Im N_{prior}(x,y) - Im N_{post}(x',y')| \quad 11$$

The pair  $(center_x, center_y)$  is the coordinate of the center point of the limb from one image.

$$D = \{(a,b,\theta) \mid a_1 < a < a_2, b_1 < b < b_2, \theta_1 < \theta < \theta_2\} \quad 12$$

25

is the parameter (searching) space. The problem is to determine the ( $center_x$ ,  $center_y$ ) and the searching space  $\{a_1, a_2, b_1, b_2, \theta_1, \theta_2\}$ . The limbus is manually located in this embodiment on both images to obtain the center coordinate ( $center_x$ ,  $center_y$ ) from the measurement system, and the center coordinate ( $center_{xx}$ ,  $center_{yy}$ ) from the surgical system. Then the search region is defined as

$$a_1 = center_{xx} - k, \quad a_2 = center_{xx} + k \quad 13$$

$$b_1 = center_{yy} - k, \quad b_2 = center_{yy} + k \quad 14$$

where  $k$  is a integer. The searching resolution is  $\Delta\theta = 0.5^\circ$ , and the search range is  $\pm 15^\circ$ ; so  $\theta_1 = -15^\circ$ ,  $\theta_2 = +15^\circ$ . The summation  $\sum$  is taken over a reference area  $(x, y) \in \Omega$ . The reference area is manually located to satisfy the assumption mentioned above.

### The System and Method of the Second Embodiment

The second embodiment of the present invention includes an orientation system **40** for eye surgery for correcting at least astigmatism, which is shown schematically in FIG. 9. A means for making two alignment marks **41,42** on an eye **43** of a patient with the patient in a first position may comprise, for example, an ink pen **44**, although this is not intended as a limitation, and alternative marking means known in the art may also be contemplated for use. In current use, the first position typically comprises a seated upright position. In a preferred embodiment, the marks **41,42** are made at the "3 o'clock" and "9 o'clock" positions to the eye's sclera **45** just outside the limbal margin **46**. In other words, the marks **41,42** are made at approximately the  $\pi/2$  and  $3\pi/2$  radial positions relative to the limbus **46**, with a 0 radial position comprising a top point of the limbus **46**. Thus the marks **41,42** are made substantially collinear with a diameter of the limbus **46**.

A camera, preferably a color video camera **47**, is provided for imaging the eye with the patient in a second position different from the first position. Typically the second position comprises a prone position.

The system **40** also comprises a computer **48** that has input and output means. One input **49** is in electronic connection with the camera **47**. Means are also in communication with the computer's input and output means for displaying the eye

image to an operator (FIG. 9). Such a display means may comprise, for example, a color video display monitor 50. An operator input device, which may comprise, for example, a mouse 51, is also in electronic communication with another input 52 to the computer 48. Alternatively, other operator input devices may be contemplated; for example, the monitor 50 may comprise a touch screen.

In a preferred embodiment, the corrective system 53 to be used in performing surgery, for example, laser ablation surgery on the cornea, comprises an eye tracker 54 as discussed above. In this embodiment, the monitor 50 displays both a tracked eye image 55 and an untracked eye image 56 (FIG. 10).

A first software routine 57 is resident in the computer 48 for routing the eye images to the monitor 50 and also for superimposing a graphical reticle 58 onto the tracked eye image 55. The first software 57 further permits the reticle 58 to be moved by the operator under control of the mouse 51. The reticle 58 comprises a circle 59 for superimposing on the eye's limbus 46 and a cross-hair including a pair of perpendicular lines 60,61, both of which are substantially diametric with the circle 59. Typically the generally horizontal line 60 is used to align with the alignment marks 41,42 on the eye 43. In a color system, the reticle 58 comprises a color for contrasting with the eye 43, such as, but not limited to, yellow.

The monitor 50 preferably comprises a graphical user interface 62 that has an interactive control sector 63 thereon. As shown in the exemplary screen of FIG. 10, the control sector 63 comprises a plurality of control sectors, in the form of "buttons," the activation of which moves the reticle 58 in a desired direction. Here the buttons comprise two for horizontal movement, "left" 64 and "right" 65, two for vertical movement, "up" 66 and "down" 67, and two for rotation, counterclockwise 68 and clockwise 69. Clicking on these buttons 64-69 with the mouse 51 causes motion of the reticle 58 on the interface 62 in the indicated direction, as mediated by the first software 57 (see rotated reticle in FIG. 9).

In addition, a button 71 performs recentering of the lines 60,61 over the cornea.

A second software routine 71 is also resident in the computer 48 for calculating an orientational change to be applied to a corrective surgical procedure.

The procedure, also resident in the computer 48, is to be performed on the eye 43 with the patient in the second position. Such a procedure may comprise, for example, an ablation correction profile that had been determined by a measurement system 71 in electronic communication with the computer 48, with the patient in the first position.

It will be understood based on the teachings of the present invention that in addition to images viewed on the surface of the eye, the position of the retina and any movement thereof may be determined using the above methods to view images on the retina. In the same way that the scleral blood vessels are stationary relative to the corneal surface, the retinal blood vessels are also stationary relative to the cornea. By way of example, the video camera may be replaced by a scanning laser ophthalmoscope, as disclosed in U.S. Pat. No. 6,186,628 to Van de Velde, which disclosure is hereby incorporated by reference; a retinal nerve fiber layer analyzer, as disclosed in U.S. Pat. No. 5,303,709 to Dreher et al., which disclosure is hereby incorporated by reference; or a fundus camera to provide images of blood vessel patterns that can be used in the same manner as scleral blood vessels as herein described.

In the foregoing description, certain terms have been used for brevity, clarity, and understanding, but no unnecessary limitations are to be implied therefrom beyond the requirements of the prior art, because such words are used for description purposes herein and are intended to be broadly construed. Moreover, the embodiments of the apparatus illustrated and described herein are by way of example, and the scope of the invention is not limited to the exact details of construction.

Having now described the invention, the construction, the operation and use of preferred embodiment thereof, and the advantageous new and useful results obtained thereby, the new and useful constructions, and reasonable mechanical equivalents thereof obvious to those skilled in the art, are set forth in the appended claims.

**What is claimed is:**

1. An orientation system for corrective eye surgery comprising:  
means for performing a first image mapping an eye of a patient in a first  
5 position using a predetermined eye feature;  
means for processing the first image map to determine an edge  
location of the feature in two dimensions;  
means for performing a second image mapping of the eye of the  
patient in a second position different from the first position using the feature;  
10 means for processing the second image map to locate the feature; and  
software means for calculating an orientational change to be applied  
to a corrective surgical procedure to be performed on the eye with the patient in the  
second position, the procedure comprising a correction profile determined with the  
patient in the first position.

15

2. The system recited in Claim 1, wherein the first image mapping  
performing means comprises a charge-coupled-device camera having means for  
capturing a video image.

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3. The system recited in Claim 1, wherein the first image mapping  
performing means comprises one of a scanning laser ophthalmoscope and a retinal  
nerve fiber layer analyzer.

25

4. The system recited in Claim 2, wherein the predetermined eye feature  
comprises a portion of a blood vessel in a sclera of the eye.

5. The system recited in Claim 1, wherein the first image map processing  
means comprises means for filtering the first image map to reduce noise.

30

6. The system recited in Claim 5, wherein the filtering means comprises  
a Gauss filter.

7. The system recited in Claim 1, wherein the first image map processing means comprises means for defining at least one edge of the predetermined eye feature.

5 8. The system recited in Claim 7, wherein the defining means comprises means for defining a plurality of edge locations in two dimensions.

9. The system recited in Claim 8, wherein the first image map processing means further comprises means for reducing noise in the first image map.

10. The system recited in Claim 8, wherein the first image map processing means further comprises means for providing a mapping of edge locations.

11. The system recited in Claim 10, wherein the mapping providing means  
15 comprises a thin function.

12. The system recited in Claim 1, wherein the predetermined correction profile comprises a desired corneal profile to be achieved with an excimer laser, and the orientational change calculating means comprises means for reorienting a  
20 coordinate system of the laser.

13. An orientation system for corrective eye surgery comprising:  
means for performing a first image mapping an eye of a patient in a first position using a predetermined eye feature;  
25 means for processing the first image map to determine an edge location of the feature in two dimensions;  
means for performing an objective measurement on the eye to determine a desired correction profile for improving visual acuity in the eye;  
means for performing a second image mapping of the eye of the  
30 patient in a second position different from the first position using the feature;  
means for processing the second image map to locate the feature; and



software means for calculating an orientational change to be applied to the correction profile with the patient in the second position.

5       **14.** An orientation system for eye surgery for correcting astigmatism comprising:

means for making two alignment marks on an eye of a patient, the patient in a first position;

means for imaging the eye with the patient in a second position different from the first position;

10       a computer having input and output means, the input means in electronic connection with the imaging means;

an operator input device in electronic communication with the computer input means;

15       means in communication with the computer input and output means for displaying the eye image to an operator;

first software means resident in the computer for superimposing a graphical reticle means onto the eye image on the displaying means and for permitting the graphical reticle means to be moved by the operator under control of the operator input means, the reticle means comprising a line for aligning with the two alignment marks; and

20       second software means resident in the computer for calculating an orientational change to be applied to a corrective surgical procedure to be performed on the eye with the patient in the second position, the procedure comprising a correction profile determined with the patient in the first position.

25

**15.** The system recited in Claim 14, wherein the mark making means comprises an ink pen.

30       **16.** The system recited in Claim 14, wherein the two alignment marks are made at approximately  $\pi/2$  and  $3\pi/2$  radial positions relative to a limbus of the eye, with a 0 radial position comprising a top point of the limbus.

17. The system recited in Claim 16, wherein the two alignment marks are made adjacent a limbus of the eye.

5 18. The system recited in Claim 14, wherein the imaging means comprises a video camera.

19. The system recited in Claim 18, wherein the camera comprises a color video camera.

10 20. The system recited in Claim 14, wherein the displaying means comprises a video display monitor.

15 21. The system recited in Claim 20, wherein the video display monitor comprises a color display monitor and the reticle means comprises a color for contrasting with the eye.

22. The system recited in Claim 14, wherein:  
the two alignment marks are made substantially collinear with a diameter of a limbus of the eye;  
20 the reticle means further comprises a circle for superimposing on the limbus; and  
the line is substantially diametric with the circle.

23. The system recited in Claim 22, wherein the line comprises a first line,  
25 and the reticle means further comprises a second line substantially perpendicular with the first line.

24. The system recited in Claim 14, wherein the display means comprises a graphical user interface having an interactive control sector thereon, an activation  
30 of the sector using the user input means causing a movement of the reticle means on the interface.

25. The system recited in Claim 24, wherein the control sector comprises a plurality of control sectors comprising two control sectors for horizontal movement, two control sectors for vertical movement, and two control sectors for rotation.

5 26. The system recited in Claim 25, wherein the control sectors further comprise a control sector for centering the reticle means over a cornea of the eye.

27. The system recited in Claim 14, further comprising means for tracking eye movement, and wherein the displaying means further comprises means for  
- 10 displaying a tracked eye image.

28. A method for orienting a corrective program for eye surgery comprising the steps of:

performing a first image mapping of an eye of a patient in a first  
15 position using a predetermined eye feature;

processing the first image map to determine an edge location of the feature in two dimensions;

performing a second image mapping of the eye of the patient in a second position different from the first position using the feature;

20 processing the second image map to locate the feature; and

calculating an orientational change to be applied to a corrective prescription for a surgical procedure to be performed on the eye with the patient in the second position, the procedure comprising a correction profile determined with the patient in the first position.

25 29. The method recited in Claim 28, wherein the first image mapping performing step comprises capturing a video image with a charge-coupled-device camera.

30. The method recited in Claim 28, wherein the first image mapping performing step comprises capturing a video image with one of a scanning laser ophthalmoscope and a retinal nerve fiber layer analyzer.

5 31. The method recited in Claim 28, wherein the predetermined eye feature comprises a portion of a blood vessel in a sclera of the eye.

32. The method recited in Claim 28, wherein the first image map processing step comprises filtering the first image map to reduce noise.

10 33. The method recited in Claim 32, wherein the filtering step comprises applying a Gauss filter on the first image map.

15 34. The method recited in Claim 28, wherein the first image map processing step comprises defining at least one edge of the predetermined eye feature.

35. The method recited in Claim 28, wherein the defining step comprises defining a plurality of edge locations in two dimensions.

20 36. The method recited in Claim 28, wherein the first image map processing step further comprises reducing noise in the first image map.

25 37. The method recited in Claim 28, wherein the first image map processing step further comprises providing a mapping of edge locations.

38. The method recited in Claim 37, wherein the mapping providing step comprises applying a thin function to the first image map.

30 39. The method recited in Claim 28, wherein the corrective surgical procedure comprises a desired corneal profile to be achieved with an excimer laser,

and the orientational change calculating step comprises reorienting a coordinate system of the laser.

5           **40.**   A method for orienting a corrective program for eye surgery comprising the steps of:

                  making two alignment marks on an eye of a patient, the patient in a first position;

                  imaging the eye with the patient in a second position different from the first position;

10           displaying the eye image to an operator;

                  electronically superimposing a graphical reticle means onto the eye image, the reticle means comprising a line;

                  moving the graphical reticle means to align the line with the two alignment marks; and

15           automatically computing an orientational change to be applied to a corrective surgical procedure to be performed on the eye with the patient in the second position, the procedure comprising a correction profile determined with the patient in the first position.

20           **41.**   The method recited in Claim 40, wherein the mark making step comprises marking with an ink pen.

**42.**   The method recited in Claim 40, wherein the two alignment marks are made at approximately  $\pi/2$  and  $3\pi/2$  radial positions relative to a limbus of the eye, with a 0 radial position comprising a top point of the limbus.

**43.**   The method recited in Claim 42, wherein the two alignment marks are made adjacent a limbus of the eye.

30           **44.**   The method recited in Claim 40, wherein the imaging step comprises using a video camera to image the eye.

45. The method recited in Claim 44, wherein the camera comprises a color video camera.

5 46. The method recited in Claim 40, wherein the displaying step comprises using a video display monitor to display the eye image.

47. The method recited in Claim 46, wherein the video display monitor comprises a color display monitor and the reticle means comprises a color for contrasting with the eye.

- 10 -

48. The method recited in Claim 40, wherein:  
the two alignment marks are made substantially collinear with a diameter of a limbus of the eye;  
the reticle means further comprises a circle for superimposing on the  
15 limbus; and  
the line is substantially diametric with the circle.

49. The method recited in Claim 40, wherein the line comprises a first line, and the reticle means further comprises a second line substantially perpendicular with the first line.  
20

50. The method recited in Claim 40, wherein the displaying step comprises using a graphical user interface having an interactive control sector thereon to display the eye, the sector activatable to cause a movement of the reticle means on  
25 the interface.

51. The method recited in Claim 50, wherein the control sector comprises a plurality of control sectors comprising two control sectors for horizontal movement, two control sectors for vertical movement, and two control sectors for rotation.  
30

52. The method recited in Claim 51, wherein the control sectors further comprise a control sector for centering the reticle means over a cornea of the eye.

53. The method recited in Claim 40, further comprising the step of tracking  
5 eye movement, and wherein the displaying step further comprises displaying a tracked eye image.

54. A method of aligning an eye, comprising the steps of:  
(a) obtaining a first image of an eye, the eye being in a first position;  
10 (b) locating a feature of the eye in the first image;  
(c) obtaining a second image of the eye with the eye in a second position, the second position being different from the first position;  
(d) locating the feature of the eye in the second image;  
(e) comparing the location of the feature in the first position to the  
15 location of the feature in the second position; and  
(f) calculating a change in orientation of the eye from the first position to the second position based on the comparison of the of the location of the feature in the first position to the location of the feature in the second position.

20 55. The method recited in Claim 54, wherein the feature comprises a sclera blood vessel.

56. The method recited in Claim 54, wherein the feature comprises a retinal  
25 blood vessel.

57. The method recited in Claim 54, wherein the feature comprises a retinal  
nerve.

58. The method recited in Claim 54, wherein the first image and the  
30 second image are obtained by a charge-couple-device camera.

59. The method recited in Claim 54, wherein the first image and the second image are obtained using a scanning laser ophthalmoscope.

5 60. The method recited in Claim 54, wherein the first image and the second image are obtained using a retinal nerve fiber layer analyzer.

61. A method of performing laser refractive correction on an eye comprising the steps of:

- 10 (a) obtaining a first image of an eye, the eye being in a first position;
- (b) locating a feature of the eye in the first image;
- (c) calculating a laser shot pattern based on the first image of the eye;
- (d) obtaining a second image of the eye with the eye in a second position, the second position being different from the first position;
- 15 (e) locating the feature of the eye in the second image;
- (f) comparing the location of the feature in the first position to the location of the feature in the second position;
- (g) calculating a change in orientation of the eye from the first position to the second position based on the comparison of the of the location of the feature in the first position to the location of the feature in the second position; and
- 20 (h) adjusting the shot pattern of the laser based on the calculated change in orientation of the eye from the first position to the second position.

25 62. The method recited in Claim 61, wherein the feature comprises a sclera blood vessel.

63. The method recited in Claim 61, wherein the feature comprises a retinal blood vessel.

30 64. The method recited in Claim 61, wherein the feature comprises a retinal nerve.



**65.** The method recited in Claim 61, wherein the first image and the second image are obtained by a charge-couple-device camera.

**66.** The method recited in Claim 61, wherein the first image and the second  
5 image are obtained using a scanning laser ophthalmoscope.

**67.** The method recited in Claim 61, wherein the first image and the second image are obtained using a retinal nerve fiber layer analyzer.

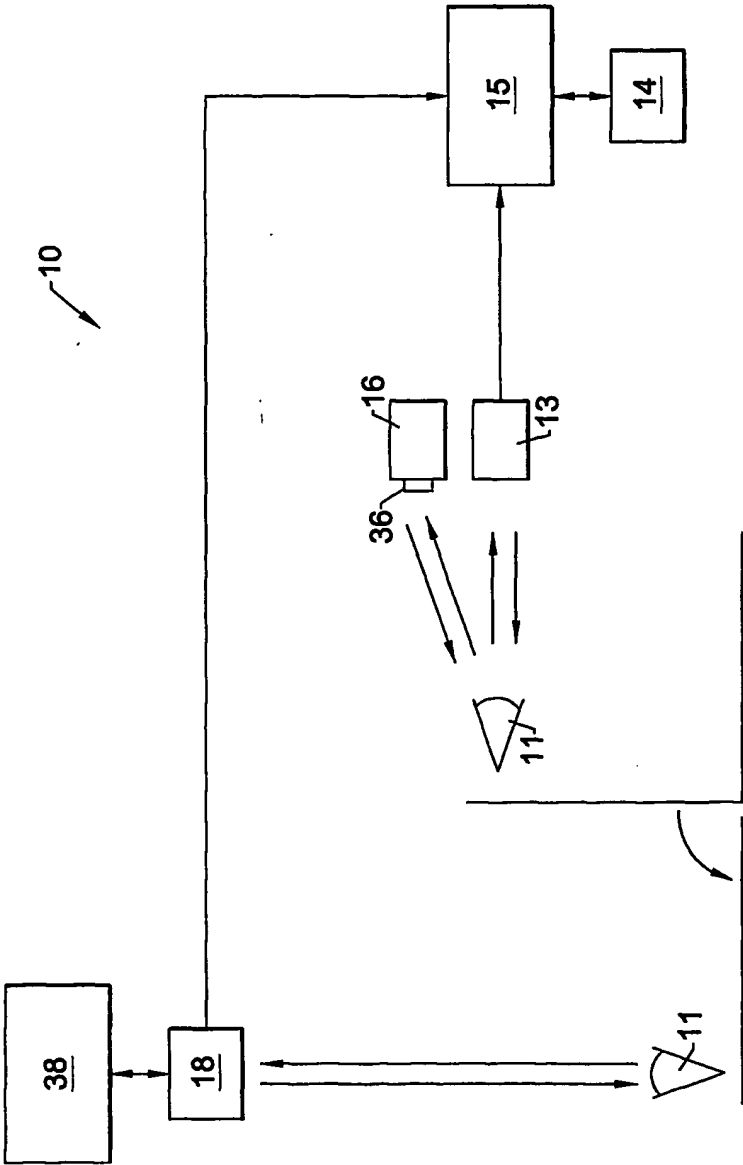


FIG. 1.

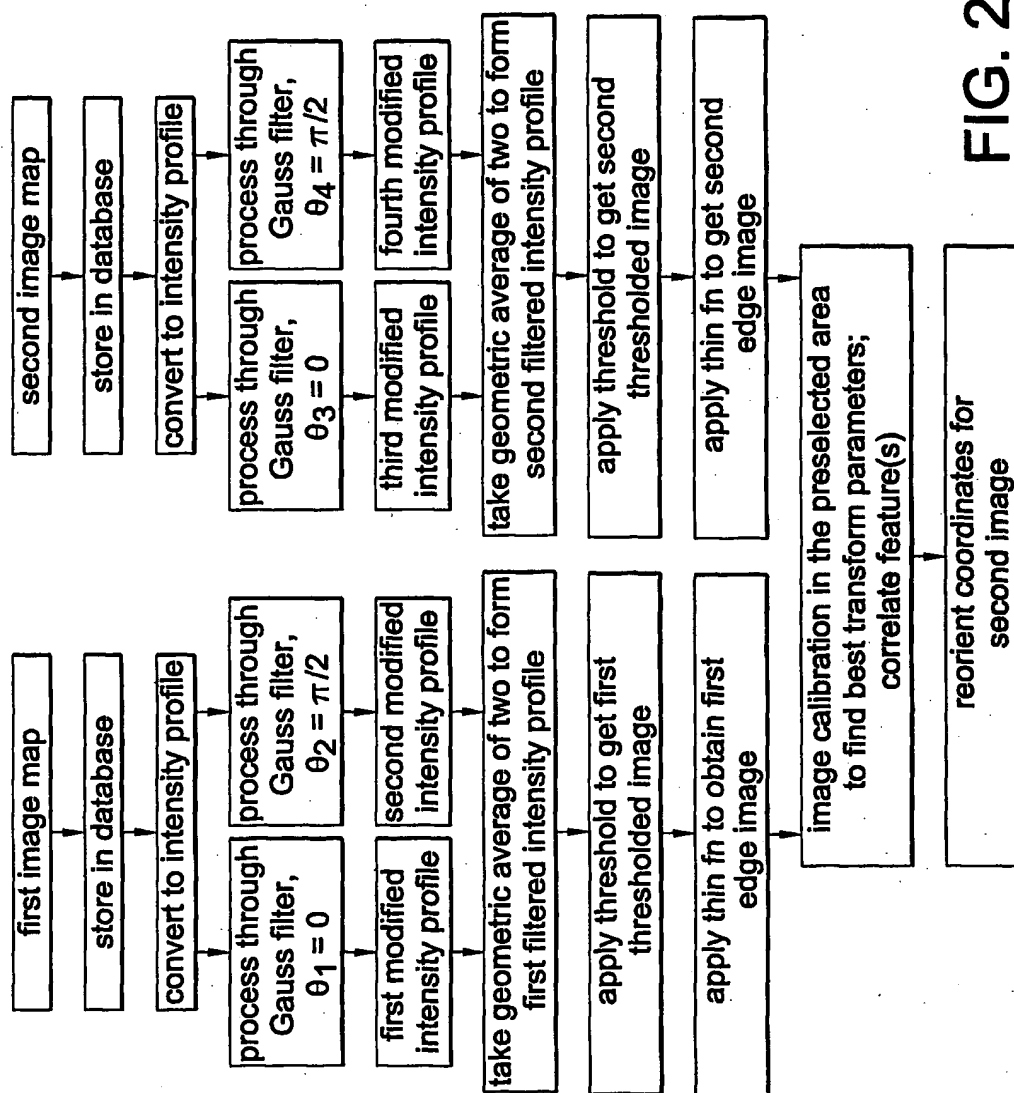


FIG. 2.

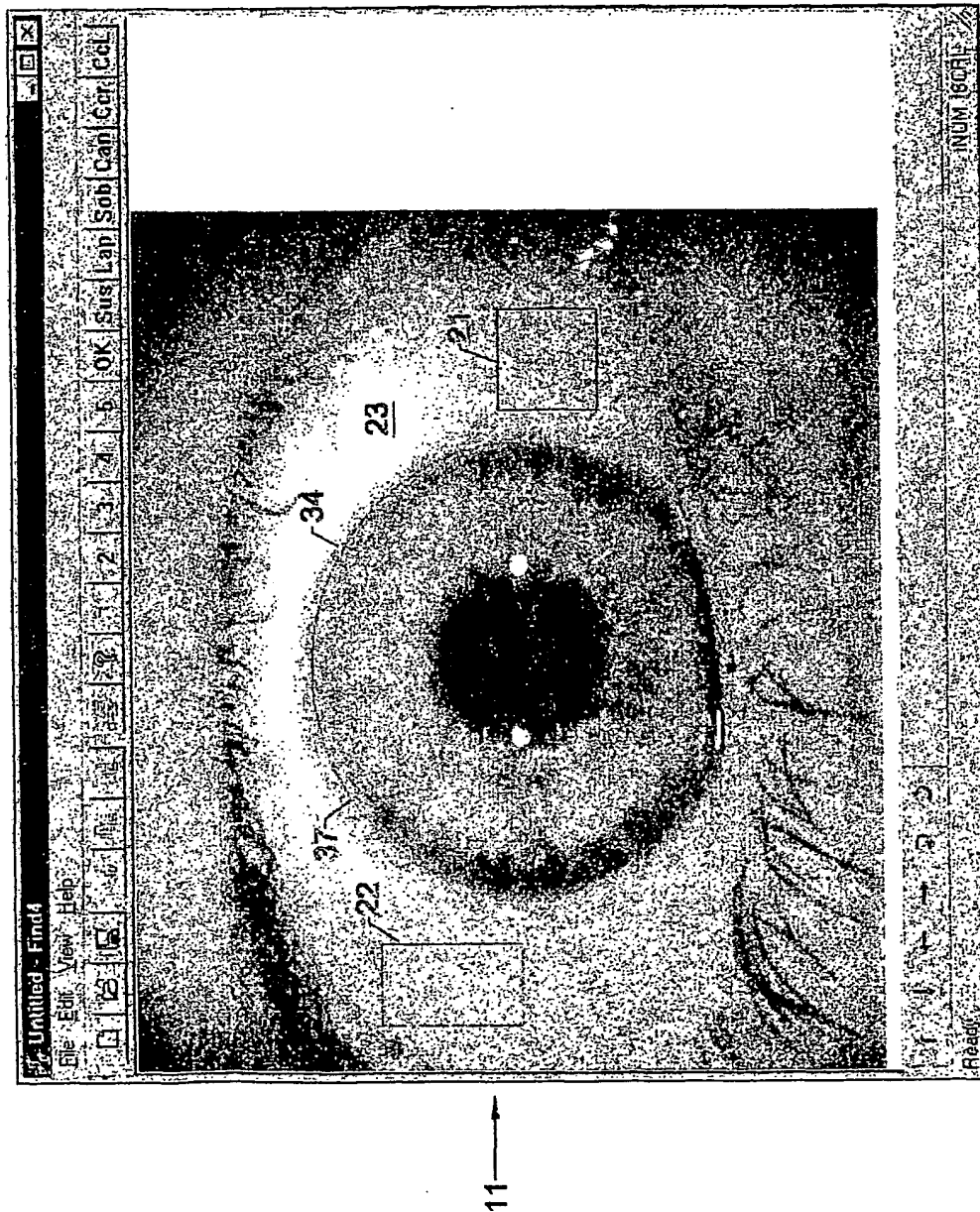


FIG. 3.

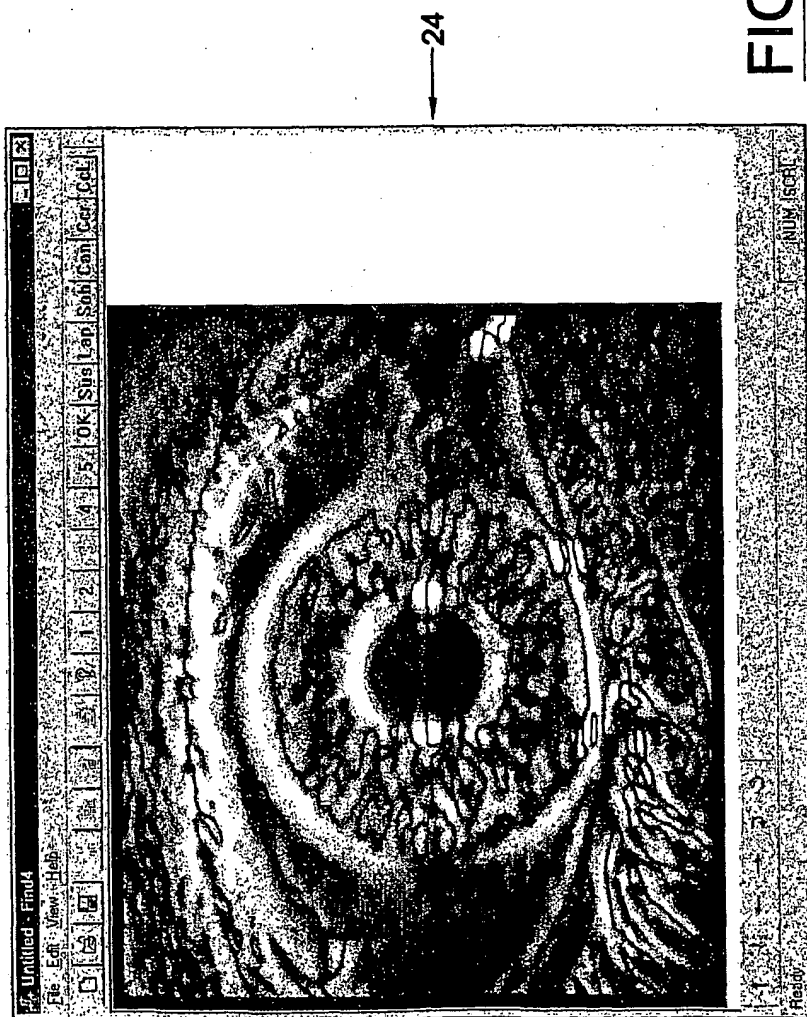
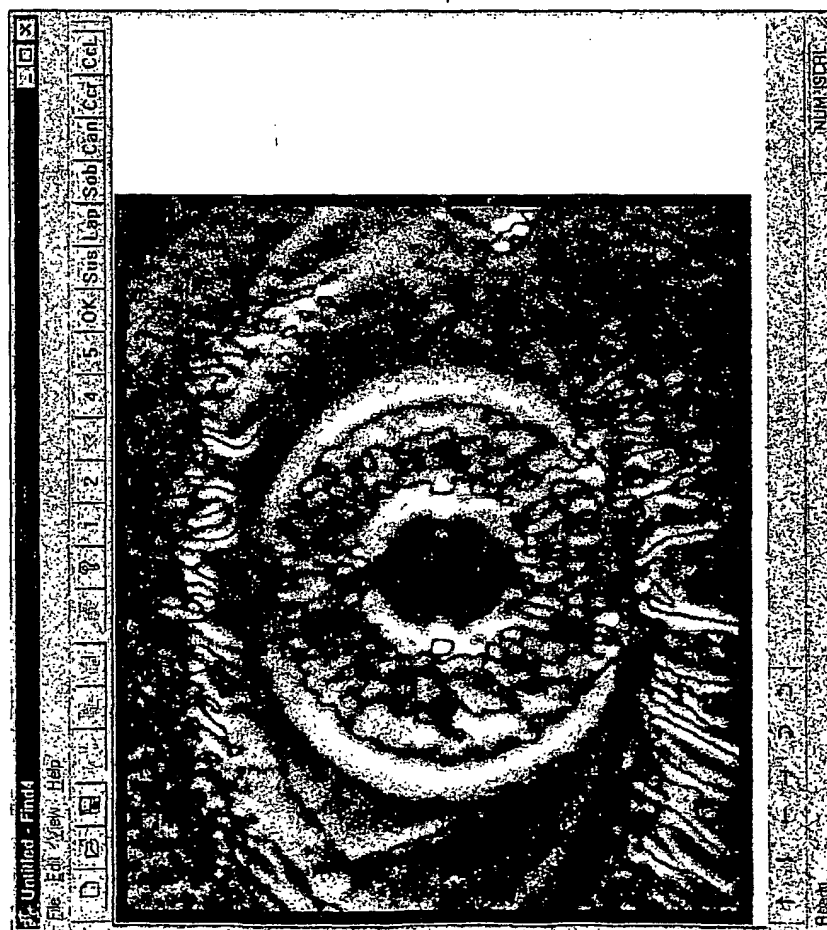


FIG. 4.



**FIG. 5.**

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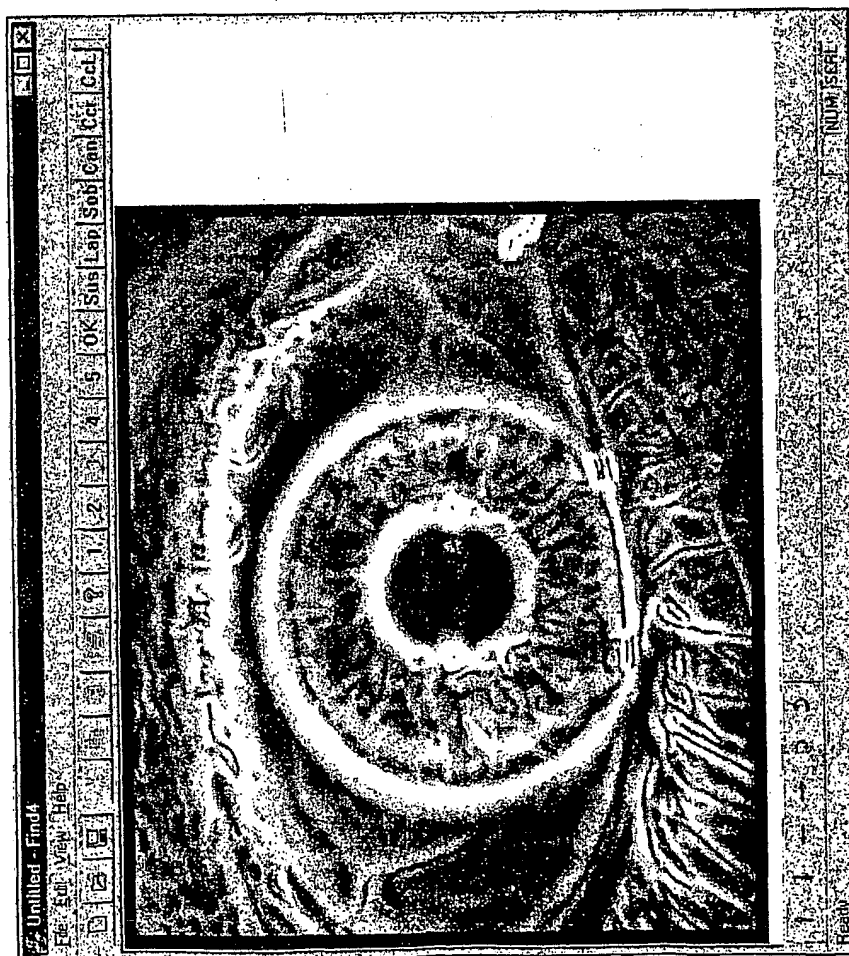
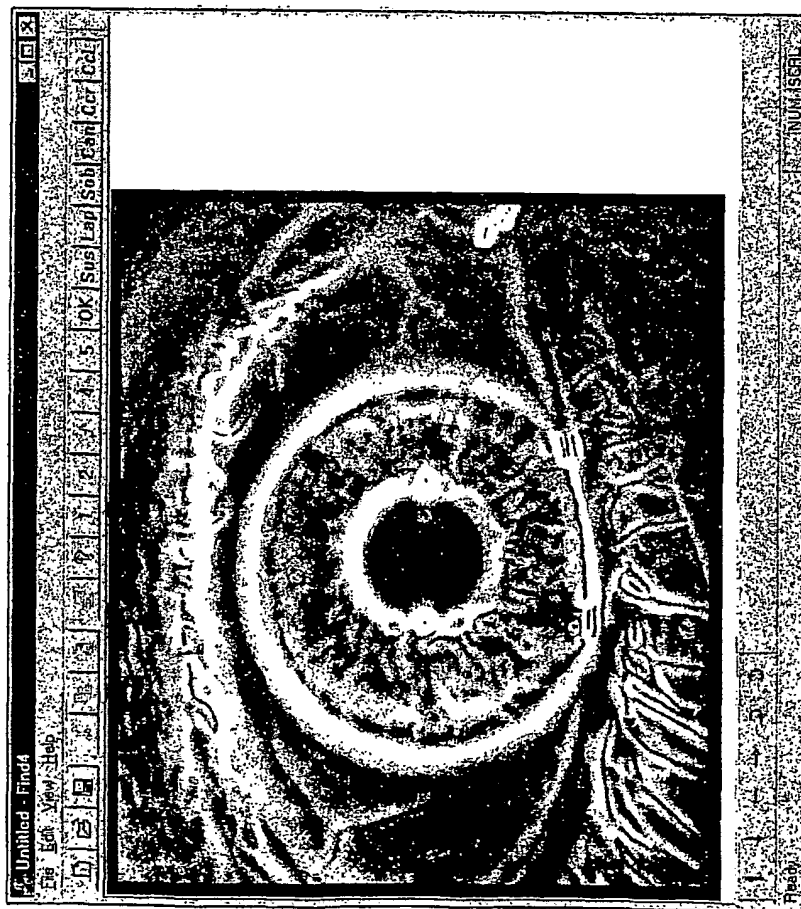


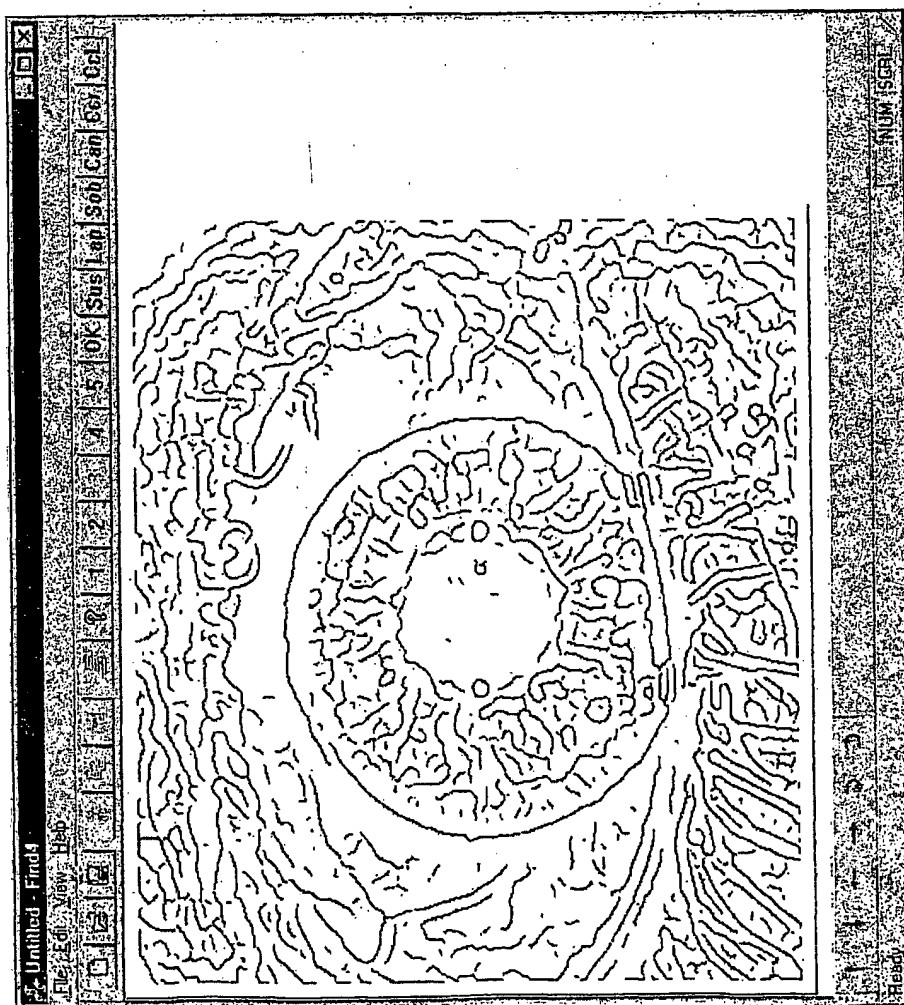
FIG. 6.



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FIG. 7.





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FIG. 8.

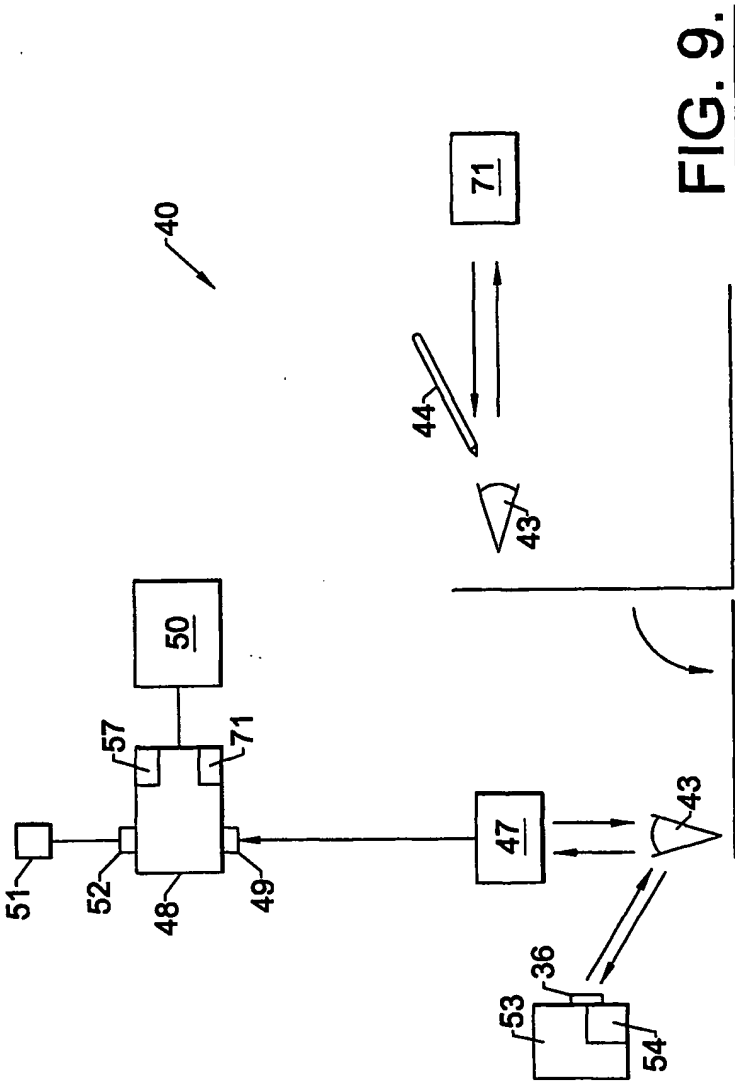
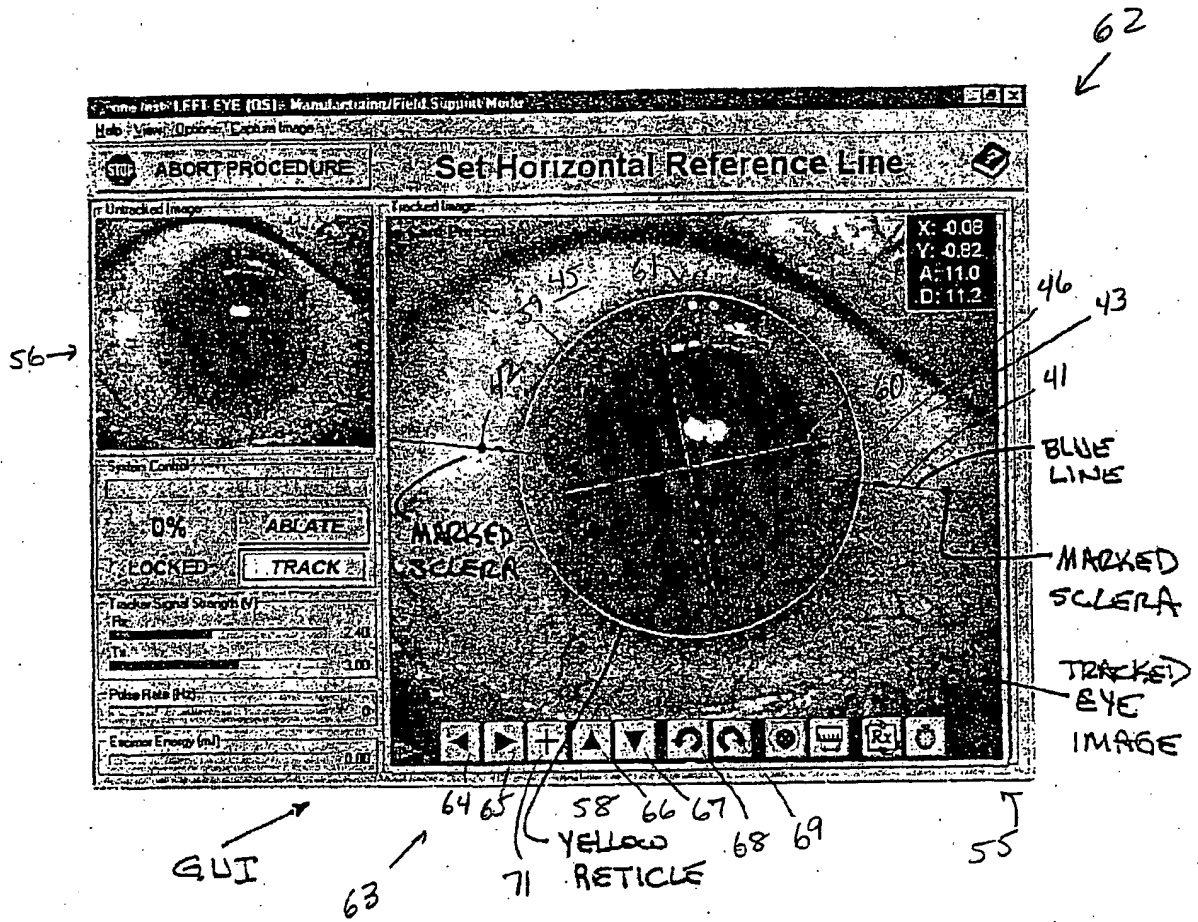


FIG. 9.



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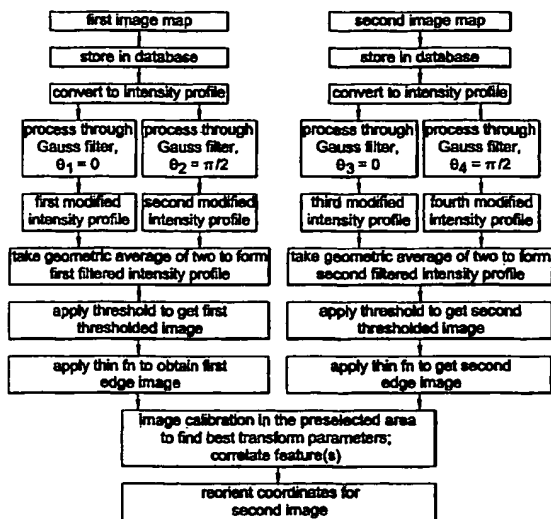
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- (74) Agent: HARTT, Jacqueline, E.; Allen, Dyer, Doppelt, Milbrath & Gilchrist, P.A., P.O.Box 3791, 255 South Orange Avenue, Suite 1401, Orlando, FL 32802-3791 (US).
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(72) Inventor: CAMPIN, John, Alfred [US/US]; 14313 N. Berwick Court, Orlando, FL 32828 (US).

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: EYE REGISTRATION AND ASTIGMATISM ALIGNMENT CONTROL SYSTEMS AND METHOD



(57) Abstract: An orientation system for corrective eye surgery includes a camera for performing a first image mapping a patient's eye using a predetermined eye feature and software for processing the first image map to determine an edge location of the feature. A second image mapping is performed with the patient in a different position. The second image map is processed to locate the feature. In a second embodiment a pen is used to make two alignment marks on the eye. The eye is imaged with the patient in another position, and the image displayed. Software superimposes a graphical reticle onto the eye image, which is movable to align with the two alignment marks. In both cases software also calculates an orientational change to be applied to a corrective prescription for a surgical procedure to be performed on the eye with the patient in the second position.

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# INTERNATIONAL SEARCH REPORT

International Application No

PC/IB 01/00805

## A. CLASSIFICATION OF SUBJECT MATTER

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According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

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IPC 7 A61F A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal, WPI Data, PAJ

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X	WO 98 00078 A (MASON WILLIAM ;LIFE SCIENCE RESOURCES LIMITED. (GB)) 8 January 1998 (1998-01-08)	1-3,7,8, 10,13, 28-30, 34,35, 37,54, 56-58,60
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Y	US 4 848 340 A (BILLE JOSEF F ET AL) 18 July 1989 (1989-07-18)	61, 63-65,67
A	column 7, line 44 -column 8, line 18; figure 4	14,40
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International Application No  
PC1/IB 01/00805

C(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT		
Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	EP 0 456 166 A (NIHON KOHDEN CORP ;YAGI TOSHIAKI (JP)) 13 November 1991 (1991-11-13) abstract; figure 6 ---	1,28,54
A	US 5 614 967 A (ISHIKAWA NORIO ET AL) 25 March 1997 (1997-03-25) column 6, line 4 - line 40; figures 3A,3B -----	1,13,28, 54,61

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